

## **REMARKS/ARGUMENTS**

### **Status of the Claims**

Claims 1 to 8 and 50 to 52 were previously undergoing examination. Claim 1 is amended. No amendment is an acquiescence to a position adopted by the Office. Claims 53 to 63 are new. Claims 9 to 49 were previously canceled without prejudice.

After entry of these amendments, claims 1 to 8 and 50 to 63 will be pending.

Claims 1 to 8 and 50 to 52 stand rejected under 35 U.S.C. §112, first paragraph, as allegedly not satisfying the written description requirement.

Claims 1 to 8 and 50 to 52 stand rejected under the Judicially Created Doctrine of Obviousness-type Double Patenting over claims 1 to 17 of U.S. Patent No. 6,646,004.

Claims 1 to 8 and 50 to 52 stand provisionally rejected under the Judicially Created Doctrine of Obviousness-type Double Patenting over claims 16 to 22 and 24 to 30 of co-pending application No. 10/432,742

Applicants address these rejections further below.

### **Support for the Amendments to the Claims**

Claim 1 was amended to set forth an enantiomeric excess of 80%. This amount finds support, *inter alia*, in the specification at page 21, line 20 which recites a 90% optically pure composition which would correspond to an enantiomeric excess of 80% (see following paragraph of the specification for a discussion of enantiomeric excess).

New dependent claims 53 to 55 set forth an enantiomeric excess of 98%. Support for this subject matter is as set forth previously for claim 51.

New dependent claim 56 sets forth that the mammal is a human. Support for this subject matter is found, *inter alia*, in the specification at p. 9, line 14.

New dependent claims 57 to 63 are drawn to combination therapy with a second agent which is an anti-obesity agent. Support for the subject matter of these claims is found *inter alia* in the specification at p. 23, last paragraph.

Accordingly, the Applicants believe the amendments to the claims add no new matter and respectfully request their entry.

**Response to the Rejection of Claims 1 to 8 and 50 to 52 for an Alleged Lack of Written Description**

The Office contends that the specification does not convey to one of ordinary skill in the art that the inventors, at the time the application was filed, had possession of the claimed invention. Applicants note that the specification teaches that the subject compounds can be used to treat both obesity and obesity-related disorders at page 23. The specification provides a definition of obesity at p. 14, second full paragraph. At page 24, lines 19 to 24, the specification states that therapeutically effective amounts of the compounds can be used to prepare a pharmaceutical composition to treat obesity among other listed conditions. In the section beginning on page 25, the specification discloses pharmaceutical compositions and methods of administration. There is simply no critical feature which is not adequately described in the specification and which is not conventional in the art or known to one of ordinary skill in the art. Applicants submit that the specification adequately teaches all of the operations needed to practice a method of treating obesity by administering the subject compounds. As the instant rejection concerns the written description requirement of 35 U.S.C. §112, first paragraph, and not the enablement requirement of 35 U.S.C. §112, first paragraph, the Applicants have not addressed herein the enablement of the claimed subject matter. If the operability of the claimed subject matter is an issue to be addressed, kindly let us know.

Applicants further note that new claims 57 to 63 are drawn to combination therapy wherein the compositions of claim 1 are used in combination with a second agent which is an anti-obesity agent. Particularly with respect to these claims and the nature of the second agents as anti-obesity agents, one of ordinary skill in the art would appreciate the efficacy of such combination methods in treating obesity.

Accordingly, the Applicant's respectfully request that the above rejection be reconsidered and withdrawn.

**Response to the Rejection of Claims 1 to 8 and 50 to 52 under the Judicially Created Doctrine of Obviousness-type Double Patenting over claims 1 to 17 of U.S. Patent No. 6,646,004.**

Applicants acknowledge that some of the subject matter of the instant claims and those of the '004 patent may overlap and thus be subject to rejection under the Judicially Created Doctrine of Obviousness-type Double Patenting. Applicants note that such a rejection can be addressed by filing a suitable terminal disclaimer. Applicants intend to file a suitable terminal disclaimer once these claims are otherwise deemed to be in condition for allowance. Accordingly, the Applicants request that this rejection be held in abeyance until such time.

**Response to the *Provisional* Rejection of Claims 1 to 8 and 50 to 52 under the Judicially Created Doctrine of Obviousness-type Double Patenting over claims 16 to 22 and 24 to 30 of co-pending application No. 10/432,742**

Applicants acknowledge that the subject matter between the two applications may overlap and thus fall subject to a provisional rejection under the Judicially Created Doctrine of Obviousness-type Double Patenting. Applicants refer the Examiner to MPEP §804 which sets forth at p. 800-17 (*see*, August 2005 edition) the *revised* procedure to be followed with respect to such provisional rejections:

***B. Between Copending Applications—Provisional Rejections***

Occasionally, the examiner becomes aware of two copending applications >that were< filed by the same inventive entity, or by different inventive entities having a common inventor, and/or by a common assignee >, or that claim an invention resulting from activities undertaken within the scope of a joint research agreement as defined in 35 U.S.C. 103(c)(2) and (3), < that would raise an issue of double patenting if one of the applications became a patent. Where this issue can be addressed without violating the confidential status of applications (35 U.S.C. 122), the courts have sanctioned the practice of making applicant aware of the potential double patenting problem if one of the applications became a patent by permitting the examiner to make a "provisional" rejection on the ground of double patenting. *In re Mott*, 539 F.2d 1291, 190 USPQ 536 (CCPA 1976); *In re Wetterau*, 356 F.2d 556, 148 USPQ 499 (CCPA 1966). The merits of such a provisional rejection can

be addressed by both the applicant and the examiner without waiting for the first patent to issue.

The "provisional" double patenting rejection should continue to be made by the examiner in each application as long as there are conflicting claims in more than one application unless that "provisional" double patenting rejection is the only rejection remaining in >at least< one of the applications.

#### **1. Nonstatutory Double Patenting Rejections**

If a "provisional" nonstatutory obviousness-type double patenting (ODP) rejection is the only rejection remaining in the earlier filed of the two pending applications, while the later-filed application is rejectable on other grounds, the examiner should withdraw that rejection and permit the earlier-filed application to issue as a patent without a terminal disclaimer. If the ODP rejection is the only rejection remaining in the later-filed application, while the earlier-filed application is rejectable on other grounds, a terminal disclaimer must be required in the later-filed application before the rejection can be withdrawn.

If "provisional" ODP rejections in two applications are the only rejections remaining in those applications, the examiner should withdraw the ODP rejection in the earlier filed application thereby permitting that application to issue without need of a terminal disclaimer. A terminal disclaimer must be required in the later-filed application before the ODP rejection can be withdrawn and the application permitted to issue. If both applications are filed on the same day, the examiner should determine which application claims the base invention and which application claims the improvement (added limitations). The ODP rejection in the base application can be withdrawn without a terminal disclaimer, while the ODP rejection in the improvement application cannot be withdrawn without a terminal disclaimer.

The present application has the earliest effective filing date of June 4, 1999. The cited application has an earliest effective filing date of November 28, 2000. Accordingly, the Applicants believe that once the present application is otherwise deemed to be in allowable condition, it would be proper for the Examiner to withdraw any provisional double patenting rejection over the '742 application and allow the present application to proceed to issue without need of a terminal disclaimer over any patent to issue from the '742 application.

**Status of the IDS**

Applicants provide herewith a Supplemental IDS setting forth a corrected patent number, the references which could not be found in the parent files by the Examiner, and additional art. The Supplemental IDS does not include the Bardin et al. reference. This disclosure was duplicative of the Edelman et al. disclosure (Edelman et al. are chapter authors of the same pertinent part of the Bardin et al. reference text). The Applicants apologize for the duplication.

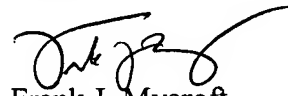
Applicants also wish to call the Examiner's attention to co-pending U.S. Patent Application No. 10/382,186 (which is also with Examiner Cook and was previously the subject of an IDS). The '186 application, as recently amended, also now presents claims drawn to methods of treating insulin resistance.

**CONCLUSION**

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 925-472-5000.

Respectfully submitted,

  
Frank J. Mycroft  
Reg. No. 46,946

TOWNSEND and TOWNSEND and CREW LLP  
Two Embarcadero Center, Eighth Floor  
San Francisco, California 94111-3834  
Tel: 925-472-5000  
Fax: 415-576-0300  
Attachments  
FJM:fjm  
60666876\_1.DOC